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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,511	01/23/2002	Matthew L. Parsons	71710-56440	9369

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GENZYME CORPORATION
LEGAL DEPARTMENT
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EXAMINER

LACYK, JOHN P

ART UNIT PAPER NUMBER

3736

DATE MAILED: 04/06/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,511

Applicant(s)

PARSONS ET AL.

Examiner

John P Lacyk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 26-68 is/are rejected.
- 7) ☒ Claim(s) 22-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 32-33, 52-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32-33 still contain the indefinite language "can be", as discussed in the previous action. Claim 2 is still considered to be directed to the intended use of the device. The claim provides no further structural limitations of the device and is merely directed to where the device is attached or adhered to. Claims 31-22 still fail to claim sufficient structure of the device. Claim 31 provides no structure to allow for the function of "enhancing of attachment". Claim 32 is still indefinite in that the claim fails to provide sufficient structure that would support or perform the function of "maximize the surface area". While the claim is read in light of the specification the claim can not rely on the specification to support missing claim language. The claim must be define a complete device and any functional language must be supported by sufficient structure in order to perform such a function. Claim 33 again provides no structural limitation to support the function of forming multiple seals such as: multiple flanges for forming multiple, independent seals. In claims 52-56, the use of the phrase "ring-type" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "-type"), thereby rendering the scope of the claim(s) unascertainable. While read in light of the specification, the claims are still indefinite in

that the specification does not specifically teach what the limitations of ring-type include other than a ring. While Figure 56 shows one embodiment the specification does not encompass all elements that would be included with such a limitation including any that are not specifically disclosed.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-6, 26-27, 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogojavlensky.

Bogojavlensky discloses a device having a housing having a top surface, sides and a flange that is adapted to adhere to the body to form a seal with the body.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 28-29, 42-47 are rejected under 35 U.S.C. 103(b) as being unpatentable over Bogojavlensky.

Although Bogojavlensky does not specifically disclose the claimed angles or range of height, width, thickness, etc. of the device, the courts have shown that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (In re Aller et al, 105 USPQ 233) and therefore would have been obvious to one skilled in the art to discover the optimum size and/or dimensions of the device.

7. Claims 1, 3-4, 7, 10, 13, 26-27, 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Argenta et al.

Argenta et al discloses a device also having a housing having a top surface and sides that is adapted to adhere to the body to form a seal with the body. Argenta et al also teaches the use of a screen or reinforcing member.

8. Claims 8-9, 28-29, 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Argenta et al.

With regard to claims 28-29, 42-47, the claims are obvious for the same reasons as discussed above. With respect to claims 8-9, the courts have shown that it is an

obvious expedient to modify the shape or form of a device (In re Dailey et al, 149 USPQ 47).

9. Claims 1-19, 26-29, 31-33, 36-52, 57-68 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Spence et al.

10. Claims 1-7, 9-21, 26-29, 31-68 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by WO 01 17437.

11. Claims 1-7, 9-19, 26, 32-33, 36, 42-49, 52 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by EP 0919193.

12. Applicant's arguments filed 1/21/2004 have been fully considered but they are not persuasive.

13. In response to applicant's argument that Bogojavlensky and Argenta are not directed to a device adapted for adherence to an internal organ, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See

In re Casey, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicant's argument with respect to Spence et al is unclear, applicant states that Spence is directed to a device for stabilizing the heart using a suction cup and then argues that Spence does not have a portion adapted for adherence to an internal organ. It appears that the heart is in fact an internal organ and the device is attached to the surface, thereby having a portion adapted for adherence. Similarly with respect to WO 0117437 which applicant states is directed to a device for manipulating an organ using a suction cup, which appears to clearly read on the claimed limitations. It is unclear what claimed limitations define over the art. Further with respect to EP 0919193 which applicant states is directed to a device for stabilizing tissue by connecting the device to the tissue. While some of the art may teach stabilizing the organ, this is considered to be a manipulation of the organ since it alters the natural position and/or movement of the organ.

14. Claims 22-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P Lacyk whose telephone number is 703-308-2995.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John P Lacyk
Primary Examiner
Art Unit 3736

J.P. Lacyk